

REMARKS

Minor amendments have been made to claims 1 and 7 to respond to the Examiner's objections discussed in the first section of the September 11, 2006 office action. Claim 1 has been amended to specify that the body wall tissue comprises "a multilaminate, stratified structure comprising differentiated tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity." Support for this claim amendment is found, for example, on page 1, lines 26-31 of the application as filed.

Rejection of Claims 1, 3, 4, and 6-9 Under 35 U.S.C. § 102(b)-

The Examiner has rejected claims 1, 3, 4, and 6-9 under 35 U.S.C. § 102(b) as being anticipated by WO 98/25637. Applicant respectfully traverses the Examiner's rejection. As amended, claims 1, 3, 4, and 6-9 are not anticipated by WO 98/25637.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). The Examiner contends that WO 98/25637 anticipates the repair of connective tissue such as skin and muscle. Claim 1, and its dependent claims 2-9 have been amended to require that the body wall tissue comprises "a multilaminate, stratified structure comprising differentiated tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity." The Examiner does not argue that WO 98/25637 anticipates the repair of the other specific differentiated tissue types in the combination of multilaminate, stratified differentiated tissue types specified in Applicant's amended claims 1-9 (*i.e.*, connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity). Thus, WO

98/25637 does not anticipate Applicant's amended claims. Withdrawal of the rejection of claims 1, 3, 4, and 6-9 under 35 U.S.C. § 102(b) as being anticipated by WO 98/25637 is respectfully requested.

Rejection of Claims 1-9 Under 35 U.S.C. § 103(a)-

The Examiner has rejected claims 1-9 under 35 U.S.C. § 103(a) as being obvious over WO 98/25637 in view of U.S. Patent No. 5,955,110 (hereinafter the '110 patent). Applicant respectfully traverses the Examiner's rejection. As amended, claims 1-9 are not obvious over WO 98/25637 in view of the '110 patent.

Applicant's amended claims 1-9 specify the repair of body wall tissue that comprises a multilaminate, stratified structure comprising a combination of differentiated tissue types that are specified in Applicant's amended claims including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity. The '110 patent describes graft compositions comprising intestinal submucosa tissue, and discloses the use of those graft compositions for the repair of hernias and gastroschisis. WO 98/25637 describes graft compositions comprising liver basement membrane. The graft compositions described in WO 98/25637 are not compositionally and structurally identical to those described in the '110 patent. Accordingly, it is not obvious that the liver-derived graft compositions described in WO 98/25637, which are not compositionally and structurally identical to the intestinal tissue-derived graft compositions described in the '110 patent, could substituted for the compositions described in the '110 patent and could be used to effectively repair *in vivo* a complex structure such as "a multilaminate, stratified structure comprising differentiated tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity."

Applicants statement, cited by the Examiner, that liver basement membrane

tissue “can be substituted for intestinal submucosa tissue in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation” refer to general effects of liver basement membrane graft compositions. These statements do not mean that because liver basement membrane compositions cause growth-promoting effects it is obvious that they would be effective in repairing *in vivo* the **complex structure** of Applicant’s amended claims 1-9 (*i.e.*, “a multilaminate, stratified structure comprising differentiated tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity”). Thus, Applicant’s amended claims 1-9 are not obvious over WO 98/25637 in view of the ‘110 patent. Withdrawal of the rejection of claims 1-9 under 35 U.S.C. § 103(a) as being obvious over WO 98/25637 in view of the ‘110 patent is respectfully requested.

Provisional Rejection of Claims 1-9 For Obviousness-Type Double Patenting-

The Examiner has provisionally rejected claims 1-9 as being unpatentable for obviousness-type double patenting over claims 24 and 25 of co-pending application number 10/755,386 in view of the ‘110 patent and WO 98/25637. It is believed that the Examiner meant to reject the claims for obviousness-type double patent over co-pending application number 10/775,386, rather than application number 10/755,386. Application number 10/775,386 (hereinafter the ‘386 application) is a continuation application in a line of continuation applications of the U.S. national application that was based on the PCT application that published as WO 98/25637. Applicant respectfully traverses the Examiner’s rejection. As amended, claims 1-9 are not obvious over claims 24 and 25 of the ‘386 application in view of the ‘110 patent and WO 98/25637.

Applicant's amended claims 1-9 specify the repair of body wall tissue that comprises a "multilaminate, stratified structure comprising a combination of differentiated tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity." The '110 patent describes graft compositions comprising intestinal submucosa tissue and their use for the repair of hernias and gastroschisis. Claims 24 and 25 of the '386 application are directed to a method for tissue repair using gelled liver basement membrane compositions, and WO 98/25637 describes graft compositions comprising liver basement membrane. The graft compositions claimed in the '386 application and described in WO 98/25637 are not compositionally and structurally identical to those described in the '110 patent. Accordingly, as discussed above, it is not obvious that the liver-derived graft compositions claimed in the '386 application or described in WO 98/25637, which are not compositionally and structurally identical to the intestinal tissue-derived graft compositions described in the '110 patent, could be substituted for the graft compositions described in the '110 patent and could be used to effectively repair *in vivo* a complex structure such as "a multilaminate, stratified structure comprising differentiated tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity." Thus, Applicant's amended claims 1-9 are not obvious over claims 24 and 25 of the '386 application in view of the '110 patent and WO 98/25637. Withdrawal of the rejection of claims 1-9 for obviousness-type double patenting is respectfully requested.

Rejection of Claims 1-9 For Obviousness-Type Double Patenting-

The Examiner has rejected claims 1-9 as being unpatentable for obviousness-type double patenting over claims 1-3 and 9 of U.S. Patent No. 6,793,939 (hereinafter the '939 patent) in view of the '110 patent and WO 98/25637. The '939 patent is a continuation

application of the U.S. national application that was based on the PCT application that published as WO 98/25637. Applicant respectfully traverses the Examiner's rejection. As amended, claims 1-9 are not obvious over claims 1-3 and 9 of the '939 patent in view of the '110 patent and WO 98/25637.

Applicant's amended claims 1-9 specify the repair of body wall tissue that comprises a "multilaminate, stratified structure comprising a combination of differentiated tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity." The '110 patent describes graft compositions comprising intestinal submucosa tissue and their use for the repair of hernias and gastroschisis. Claims 1-3 and 9 of the '939 patent are directed to a method for tissue repair using liver basement membrane compositions, and WO 98/25637 describes those liver basement membrane compositions. The graft compositions claimed in the '939 patent and described in WO 98/25637 are not compositionally and structurally identical to those described in the '110 patent. Accordingly, as discussed above, it is not obvious that the liver-derived graft compositions claimed in the '939 patent and described in WO 98/25637 could be substituted for those described in the '110 patent and used to effectively repair *in vivo* a complex structure such as "a multilaminate, stratified structure comprising differentiated tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue, and the serous lining of the body wall cavity." Thus, Applicant's amended claims 1-9 are not obvious over claims 1-3 and 9 of the '939 patent in view of the '110 patent and WO 98/25637. Withdrawal of the rejection of claims 1-9 for obviousness-type double patenting is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejections. The claims are in condition for allowance. Applicant respectfully requests allowance of the claims, and passage of the application to issuance.

Respectfully submitted,

A handwritten signature in black ink that reads "Rebecca Ball". The signature is written in a cursive, flowing style.

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